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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, *Plaintiff,* v. ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., USA, SUN PHARMACEUTICAL INDUSTRIES LIMITED, SANDOZ INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA, INC., *Defendants.*	)	Civil Action No. 07-3770 (DMC) (MF)

DEFENDANTS' RESPONSE TO ELI LILLY AND COMPANY'S COUNTERSTATEMENT TO DEFENDANTS' STATEMENT OF MATERIAL FACTS NOT IN DISPUTE IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 5,658,590

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Defendants Actavis Elizabeth LLC, Sandoz Inc., Mylan Pharmaceuticals Inc., Apotex Inc., Aurobindo Pharma Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "defendants"), submit this response to Eli Lilly and Company's ("Lilly") counterstatement to defendants' statement of material facts not in dispute in support of defendants' motion for summary judgment of invalidity of U.S. Patent No. 5,658,590:[1, 2]

1. Undisputed, except to the extent that prior to 1995,

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as Lilly admitted in its memorandum, "there would still be no reasonable assurance that atomoxetine would work to treat ADHD."[5]

2. Disputed because stimulants (such as methylphenidate and mixed amphetamine salts) were widely prescribed and considered safe and effective; and atomoxetine has many of the same side effects as stimulants and tricyclic antidepressants ("TCAs"), including additional warnings such as a "black box" warning for suicide ideation in children and adolescents, and additional side effects including severe liver injury, serious cardiovascular effects, psychotic or

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[1] Lilly's response to defendants' statement of material facts not in dispute violates Local Rule 56.1 which states, *inter alia*, "[t]he opponent of summary judgment shall furnish, with its opposition papers, a responsive statement of material facts, addressing each paragraph of the movant's statement, indicating agreement or disagreement and, if not agreed, stating each material fact in dispute and citing to the affidavits and other documents submitted in connection with the motion." Lilly's response contains legal arguments (*see, e.g.*, ¶¶ 1, 5, 10, 13) that do not appear in its memorandum. Accordingly, defendants respectfully request that the Court strike and disregard Lilly's improper response to defendants' statement of material facts.

[2] "Second Robinson Cert., Ex. __" refers to the Second Certification of Brian J. Robinson in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 5,658,590, filed concurrently herewith.

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[5] D.E. 373 at 18.

manic symptoms, bipolar disorder, aggressive behavior or hostility, allergic reactions, effects on urine outflow and priapism.[6]

3. Undisputed, except to the extent that there are varying symptoms, diagnoses and treatments for ADHD.[7]

4. Disputed that this fact is material to the extent it relates to the etiology and pathophysiology of ADHD. Further disputed because, prior to 1995, the prior art as a whole taught that the selective inhibition of norepinephrine reuptake was responsible for desipramine's effectiveness in treating ADHD.[8]

5. Disputed that this fact is material to the extent it relates to the etiology and pathophysiology of ADHD. Further disputed because, prior to 1995, the prior art as a whole taught that the selective inhibition of norepinephrine reuptake was responsible for desipramine's effectiveness in treating ADHD.[9]

6. Disputed. Prior to 1995, the prior art as a whole taught that the selective inhibition of norepinephrine reuptake was responsible for desipramine's effectiveness in treating ADHD.[10]

7. Disputed that this fact is material.

8. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion. Further disputed because the prior art suggested using a selective norepinephrine reuptake inhibitor to treat ADHD.[11]

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6 *See* Second Robinson Cert., Ex. GGG at 1-7.

7 *See, e.g.,* D.E. 291, Ex. A; *see also* D.E. 300; D.E. 373.

8 *See, e.g.,* D.E. 291, Ex. Q at 147, 170, 180; Ex. T at 73, 79; Ex. R at 777, 783. *See also* Second Robinson Cert., Ex. YY at 145.

9 *Id.*

10 *Id.*

11 *Id.*

9. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion. Further disputed because the prior art suggested that use of a selective norepinephrine reuptake inhibitor would be effective for treating ADHD.[12]

10. Disputed. "As of 1995, the stimulants remained the drug of choice for treating ADHD" and stimulants continue to be the first-line treatment today.[13]

11. Disputed. "As of 1995, the stimulants remained the drug of choice for treating ADHD" and stimulants continue to be the first-line treatment today.[14]

12. Disputed that this fact is material. Further disputed because "[a]s of 1995, the stimulants remained the drug of choice for treating ADHD, and were understood to be effective based on both NE and DA effects."[15]

13. Disputed that this fact is material. Further disputed to the extent that desipramine, a TCA, was effective in treating ADHD.[16]

14. Disputed that this fact is material to the extent it relates to drugs other than desipramine and to effects on receptors. Further disputed because desipramine was effective in treating ADHD. Additionally disputed because the prior art as a whole taught that desipramine selectively inhibited the reuptake of norepinephrine.[17] Also disputed that the TCAs were called "dirty drugs."

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12 *Id.*

13 D.E. 373 at 6. **REDACTED**

14 *Id.*

15 *Id.*

16 *See, e.g.,* Second Robinson Cert., Ex. ZZ at 684. *See also, e.g., id.*; Ex. YY; Ex. AAA; Ex. DDD; D.E. 291, Ex. Q; Ex R; Ex. S; Ex. T; Ex. U; Ex. V; Ex. Z.

17 *See, e.g.,* D.E. 291, Ex. Q at 147, 170, 180; Ex. T at 73, 79; Ex. R at 777, 783. *See also* Second Robinson Cert., Ex. YY at 145.

15. Disputed that this fact is material. Further disputed because the prior art as a whole taught that desipramine was effective in treating ADHD, and TCAs, including desipramine were a "gold-standard" treatment for ADHD until at least 2001.[18]

16. Disputed that this fact is material to the extent it relates to drugs other than desipramine. Also disputed that TCAs have ever been shown to cause sudden death.

17. Object to the phrase "These medications" as vague and indefinite. Disputed that this fact is material to the extent it relates to drugs other than desipramine. Further disputed to the extent that desipramine, a TCA, was "thought to be effective in treating ADHD," because desipramine was, in fact, effective in treating ADHD.[19]

18. Disputed that this statement is a material fact as it improperly sets forth an argument. Further dispute that defendants are using hindsight in their obviousness analysis.

19. Disputed to the extent that there is no evidence that Lilly made any samples of atomoxetine available to persons outside of Lilly other than Bolden-Watson, Dr. Biederman and Dr. Spencer.

20. Disputed that this statement is a material fact as it improperly sets forth an argument. Further disputed because the prior art suggested using a selective norepinephrine reuptake inhibitor to treat ADHD.[20]

21. Disputed that this fact is material. Further disputed because the prior art as a whole taught that desipramine—a selective norepinephrine reuptake inhibitor—was effective for ADHD.[21]

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[18] *See, e.g.,* Second Robinson Cert., Ex. ZZ at 684; Ex. HHH at 261. *See also, e.g., id.*, Ex. YY; Ex. AAA; Ex. DDD; D.E. 291, Ex. Q; Ex R; Ex. S; Ex. T; Ex. U; Ex. V; Ex. Z.

[19] *See, e.g.,* Second Robinson Cert., Ex. ZZ at 684. *See also, e.g., id.;* Ex. YY; Ex. AAA; Ex. DDD; D.E. 291, Ex. Q; Ex R; Ex. S; Ex. T; Ex. U; Ex. V; Ex. Z.

[20] *Id.*

22. Disputed that this statement is a material fact to the extent it improperly sets forth an argument. Further disputed because the U.S. Patent and Trademark Office ("USPTO") never considered the argument that defendants raise in their motion. Rather, the USPTO was told by Lilly that TCAs (including desipramine) and atomoxetine have nothing in common: "[a]tomoxetine is a highly selective and specific norepinephrine inhibitor, which is not suggested by the numerous activities of the prior art tricyclics."[22]

23. Disputed that this statement is a material fact to the extent it improperly sets forth an argument. Further disputed because the USPTO never considered the argument that defendants raise in their motion. Rather, the USPTO was misled by Lilly that TCAs (including desipramine) and atomoxetine have nothing in common: "[a]tomoxetine is a highly selective and specific norepinephrine inhibitor, which is not suggested by the numerous activities of the prior art tricyclics."[23]

24. Disputed that this fact is material.

25. Undisputed, except to the extent that it was known in 1995 that desipramine's affinity for binding to multiple receptors causes side effects and is not responsible for the effectiveness of desipramine in treating ADHD.[24]

26. Disputed. Prior to 1995, the prior art as a whole taught that desipramine is a selective norepinephrine reuptake inhibitor.[25]

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[21] *See, e.g.*, D.E. 291, Ex. Q at 147, 170, 180; Ex. T at 73, 79; Ex. R at 777, 783. *See also* Second Robinson Cert., Ex. YY at 145.

[22] D.E. 291, Ex. JJ at STPAT00000037.

[23] *Id.*

[24] *See, e.g.*, D.E. 291, Ex. R at 777-778; Ex. V at 906; Ex. Z at 64.

[25] *See, e.g.*, D.E. 291, Ex. Q at 147, 170, 180; Ex. T at 73, 79; Ex. R at 777, 783. *See also* Second Robinson Cert., Ex. YY at 145.

27. Disputed that this fact is material to the extent it relates to drugs other than desipramine and to activities of desipramine other than the selective inhibition of norepinephrine reuptake. Further disputed because, prior to 1995, the prior art as a whole taught that the selective inhibition of norepinephrine reuptake was responsible for desipramine's effectiveness in treating ADHD.[26]

28. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion. Further disputed because it was known in 1995 that desipramine's affinity for binding to multiple receptors causes side effects and is not responsible for the effectiveness of desipramine in treating ADHD. Additionally disputed because those skilled in the art did look to and continued to look to desipramine as a model; TCAs were a "gold-standard" treatment for ADHD until at least 2001.[27]

29. Disputed that this fact is material.

30. Disputed that this statement is a material fact as it improperly sets forth an argument and/or a purported expert's opinion. Further disputed because, prior to 1995, the prior art as a whole taught that the selective inhibition of norepinephrine reuptake was responsible for desipramine's effectiveness in treating ADHD.[28] For example, the 1987 Zametkin and Rapoport article that Lilly cites in its brief states that "[a] role for norepinephrine metabolism in the pathophysiology and treatment of this disorder is highly likely."[29] For another example, the 1986 Donnelly reference states that "[t]he relative pharmacologic specificity of [desipramine] for the noradrenergic system and its lack of dopaminergic activity make it of particular interest in the evaluation of noradrenergic hypotheses of ADDH and in the elucidation of possible

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26 *Id.*

27 *Id. See also, e.g.*, Ex. HHH at 261.

28 *Id.*

29 Second Robinson Cert., Ex. ZZ at 684.

mechanisms of action in the effective treatment of ADDH."[30] Those of ordinary skill

REDACTED used desipramine to treat ADHD in the 1990s.[31]

31. Disputed that this statement is a material fact as it improperly sets forth an argument and/or a purported expert's opinion. Further disputed because, prior to 1995, the prior art as a whole taught that the selective inhibition of norepinephrine reuptake was responsible for desipramine's effectiveness in treating ADHD.[32] For example, the 1987 Zametkin and Rapoport article that Lilly cites in its brief states that "[a] role for norepinephrine metabolism in the pathophysiology and treatment of this disorder is highly likely."[33] For another example, the 1986 Donnelly reference states that "[t]he relative pharmacologic specificity of [desipramine] for the noradrenergic system and its lack of dopaminergic activity make it of particular interest in the evaluation of noradrenergic hypotheses of ADDH and in the elucidation of possible mechanisms of action in the effective treatment of ADDH."[34] Those of ordinary skill

REDACTED used desipramine to treat ADHD in the 1990s.[35]

32. Disputed that this statement is a material fact as it improperly sets forth an argument and/or a purported expert's opinion. Further disputed that this statement contains any material fact to the extent it relates to non-SNRI methods of treating ADHD. Additionally disputed because, prior to 1995, the prior art as a whole taught that the selective inhibition of norepinephrine reuptake was responsible for desipramine's effectiveness in treating ADHD.[36]

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30 D.E. 291, Ex. T at 73.

31 *See* D.E. 300 at 17.

32 *See, e.g.*, D.E. 291, Ex. Q at 147, 170, 180; Ex. T at 73, 79; Ex. R at 777, 783. *See also* Second Robinson Cert., Ex. YY at 145.

33 Second Robinson Cert., Ex. ZZ at 684.

34 D.E. 291, Ex. T at 73.

35 *See* D.E. 300 at 17.

36 *See, e.g.*, D.E. 291, Ex. Q at 147, 170, 180; Ex. T at 73, 79; Ex. R at 777, 783. *See also* Second Robinson Cert., Ex. YY at 145.

For example, the 1987 Zametkin and Rapoport article that Lilly cites in its brief states that "[a] role for norepinephrine metabolism in the pathophysiology and treatment of this disorder is highly likely."[37] For another example, the 1986 Donnelly reference states that "[t]he relative pharmacologic specificity of [desipramine] for the noradrenergic system and its lack of dopaminergic activity make it of particular interest in the evaluation of noradrenergic hypotheses of ADDH and in the elucidation of possible mechanisms of action in the effective treatment of ADDH."[38] Those of ordinary skill **REDACTED** used desipramine to treat ADHD in the 1990s.[39]

33. Disputed that this statement is a material fact as it improperly sets forth an argument and/or a purported expert's opinion. The prior art taught that norepinephrine reuptake inhibitors were as a class useful in the treatment of ADHD.[40]

34. Disputed that this statement is a material fact as it improperly sets forth an argument and/or a purported expert's opinion. Further disputed because, prior to 1995, the prior art as a whole taught that the selective inhibition of norepinephrine reuptake was responsible for desipramine's effectiveness in treating ADHD.[41] For example, the 1987 Zametkin and Rapoport article that Lilly cites in its brief states that "[a] role for norepinephrine metabolism in the pathophysiology and treatment of this disorder is highly likely."[42] For another example, the 1986 Donnelly reference states that "[t]he relative pharmacologic specificity of [desipramine] for the noradrenergic system and its lack of dopaminergic activity make it of particular interest in

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37 Second Robinson Cert., Ex. ZZ at 684.

38 D.E. 291, Ex. T at 73.

39 *See* D.E. 300 at 17.

40 *See, e.g.*, D.E. 291, Ex. Q at 147, 170, 180; Ex. T at 73, 79; Ex. R at 777, 783. *See also* Second Robinson Cert., Ex. YY at 145.

41 *See id.*

42 Second Robinson Cert., Ex. ZZ at 684.

the evaluation of noradrenergic hypotheses of ADDH and in the elucidation of possible mechanisms of action in the effective treatment of ADDH."[43] Those of ordinary skill

REDACTED used desipramine to treat ADHD in the 1990s.[44]

35. Disputed that this fact is material. Those of ordinary skill

REDACTED used desipramine to treat ADHD in the 1990s.[45]

36. Disputed that this fact is material.

37. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion. A person of ordinary skill in the art knowing that atomoxetine had selective norepinephrine reuptake inhibition properties would have been motivated to try atomoxetine for treating ADHD with a reasonable expectation that it would work.

38. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion. Further disputed because TCAs were a "gold-standard" treatment for ADHD until at least 2001.[46]

39. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion. Further disputed because TCAs were a "gold-standard" treatment for ADHD until at least 2001.[47]

40. Disputed that this statement is a material fact as it improperly sets forth an argument and/or a purported expert's opinion. Further disputed because atomoxetine has many of the same side effects as stimulants and TCAs, including additional warnings such as a "black

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43 D.E. 291, Ex. T at 73.
44 *See* D.E. 300 at 17.
45 *See id.*
46 *See, e.g.*, Second Robinson Cert., Ex. HHH at 261.
47 *Id.*

box" warning for suicide ideation in children and adolescents, and additional side effects including severe liver injury, serious cardiovascular effects, psychotic or manic symptoms, bipolar disorder, aggressive behavior or hostility, allergic reactions, effects on urine outflow and priapism.[48]

41. Disputed that this fact is material.

42. Disputed that this statement is a material fact to the extent it improperly sets forth an argument. Further disputed because defendants did not copy the Strattera® drug product but merely mirrored certain portions of the Strattera® label as required by the FDA.[49]

43. Object to the phrase "numerous researchers" as vague and indefinite. Disputed because any alleged praise is directed to the compound atomoxetine.

44. Disputed because any alleged praise is directed to the compound atomoxetine. Further disputed to the extent Lilly seeks to rely on the Spencer affidavit.[50]

45. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion. Further disputed that Strattera® has enjoyed any commercial success. Object to the phrase "remarkable commercial success" as vague and indefinite.

46. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion and a recitation that is a matter of law regarding claim construction.

47. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion. Further disputed that Strattera®'s sales were

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48 *See* Second Robinson Cert., Ex. GGG at 1-7.

49 *See* D.E. 300 at 16.

50 The Spencer "affidavit" fails to meet the requirements of 35 U.S.C. § 1746; is unauthenticated, inadmissible hearsay; and is not evidence of scientific acclaim.

the result of anything other than marketing. Object to the phrase "driven by its medical benefits" as vague and indefinite.

48. Disputed that this fact is material. Further disputed because defendants did not copy the Strattera® drug product but merely mirrored certain portions of Strattera®'s label as required by the FDA.[51]

49. Disputed that this fact is material. Further disputed because defendants did not copy the Strattera® drug product but merely mirrored certain portions of Strattera®'s label as required by the FDA.[52]

50. Disputed that this fact is material.

51. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion.

52. Disputed to the extent that there is no evidence that Lilly made any samples of atomoxetine available to persons outside of Lilly other than Bolden-Watson, Dr. Biederman and Dr. Spencer.

53. Disputed that this fact is material.

54. Disputed that this fact is material.

55. Disputed that this fact is material.

56. Disputed that this fact is material.

57. Disputed that this fact is material.

58. Disputed that this fact is material.

59. Disputed that this fact is material. Further disputed because the magnitude of response (11 [52%] of 21 patients) in the Massachusetts General Hospital ("MGH") proof-of-

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[51] *See* D.E. 300 at 16.

[52] *See id.*

concept study failed to meet expectations because methodologically similar trials of methylphenidate and desipramine yielded much higher response rates, namely 87% and 89%, respectively.[53]

60. Disputed that this fact is material. Further disputed because the magnitude of response (11 [52%] of 21 patients) in the MGH proof-of-concept study failed to meet expectations because methodologically similar trials of methylphenidate and desipramine yielded much higher response rates, namely 87% and 89%, respectively.[54]

61. Disputed that this fact is material.

62. Undisputed that this language is contained in the '590 patent specification, but disputed because defendants did not copy the Strattera® drug product but merely mirrored certain portions of Strattera®'s label as required by the FDA.[55]

63. Disputed that this fact is material.

64. Disputed that this statement is a material fact to the extent it improperly sets forth an argument and/or a purported expert's opinion. Further disputed because, prior to 1995,

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as Lilly admitted in its memorandum, "there would still be no reasonable assurance that atomoxetine would work to treat ADHD."[58]

65. Disputed that this fact is material. Further disputed because, prior to 1995,

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53 *See* D.E. 291, Ex. X at 695.

54 *Id.*

55 *See* D.E. 300 at 16.

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58 D.E. 373 at 18.

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REDACTED as Lilly admitted in its memorandum, "there would still be no reasonable assurance that atomoxetine would work to treat ADHD."[61]

66. Disputed that this fact is material. Further disputed because Dr. Pliszka did not recognize atomoxetine's usefulness in treating ADHD in 2001: "[n]oradrenergic agonists (like desipramine or atomoxetine) are certainly better than placebo . . . [but] enthusiasm should be limited for compounds with action at only one neurotransmitter system until clinical trial data are available that clearly shows efficacy in ADHD."[62]

Dated: July 27, 2009

Respectfully Submitted,

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61 D.E. 373 at 18.

62 D.E. 291, Ex. W at 1804.

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